

**LOW DOSE ASPIRIN- aspirin tablet, chewable**  
**Pharbest Pharmaceuticals, Inc.**

-----  
**Drug Facts**

**Active Ingredient (in each tablet)**

Aspirin 81mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

- for the temporary relief of minor aches and pains or as recommended by your doctor
- ask your doctor about other uses for this product

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

**Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are****taking a prescription drug for**

- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding: •feel faint •vomit blood •have bloody or black stools •have stomach pain that does not get better
- allergic reaction occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

**If pregnant or breast-feeding,**

ask a health professional before use. **It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

**Other information**

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature (15°-30°C)
- avoid excess heat and moisture

**Inactive ingredients**

Corn starch, dextrose monohydrate, FD&C yellow #6, flavor, silicon dioxide, sodium saccharine and stearic acid.

## Questions?

**Adverse drug event call: (866) 562-2756 M-F 8AM - 4PM**

**PHARBEST**

**NDC 16103-0366-11**

**Manufactured in the U.S.A.**

**\*Compare to the active ingredient in BAYER® CHEWABLE ASPIRIN**

**Low Dose**

**See New Warnings Information**

**Aspirin**

**81mg Pain Reliever (NSAID)**

**1000 CHEWABLE**

**TABLETS**

**Orange Flavored**

**Aspirin Regimen**

**PHARBEST** Manufactured in the U.S.A.  
NDC 16103-0366-11

**Low Dose** \*Compare to the active ingredient in BAYER CHEWABLE ASPIRIN  
See New Warnings Information

**Aspirin**  
81mg Pain Reliever (NSAID)

**1000 CHEWABLE TABLETS**  
Orange Flavored  
Aspirin Regimen

**NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN**

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>    <b>Purpose</b> Aspirin 81 mg (NSAID)* .....Pain reliever *nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b> ■ for the temporary relief of minor aches and pains or as recommended by your doctor ■ ask your doctor about other uses for this product</p> <p><b>Warnings</b> <b>Reye's syndrome:</b> Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness. <b>Allergy Alert:</b> Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock <b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Do not use</b> ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor</p> <p><b>Ask a doctor before use if</b> ■ the stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis or kidney disease ■ you have asthma ■ you are taking a diuretic</p> <p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug for</b> ■ gout ■ diabetes ■ arthritis</p> <p><b>Stop use and ask a doctor if</b> ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ allergic reaction occurs ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present ■ any new symptoms occur ■ ringing in the ears or loss of hearing occurs</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Keep out of reach of children.</b> In case of accidental overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ drink a full glass of water with each dose ■ adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor ■ children under 12 years: consult a doctor</p> <p><b>Other information</b> ■ Tamper Evident: Do not use if safety seal under cap is broken or missing ■ store at room temperature (15°-30°C) ■ avoid excess heat and moisture</p> <p><b>Inactive ingredients</b> Corn starch, dextrose monohydrate, FD&amp;C yellow #6, flavor, silicon dioxide, sodium saccharine and stearic acid.</p> <p><b>Questions? Adverse drug event call:</b> (866) 562-2756 M-F 8AM - 4PM</p>
---	---	--

\* This product is not manufactured or distributed by Bayer® Healthcare LLC, owner of the registered trademark Bayer® Chewable Aspirin.  
Manufactured by: Pharmed Pharmaceuticals Inc. Farmingdale, NY 11735 L Rev 0413

**16103-366 11 0**

## LOW DOSE ASPIRIN

aspirin tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16103-366
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	81 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
STARCH, CORN (UNII: O8232NY3SJ)				
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
<b>Product Characteristics</b>				
Color	orange	Score	no score	
Shape	ROUND	Size	8mm	
Flavor	ORANGE	Imprint Code	PH034	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-366-05	1 in 1 CARTON	08/22/2007	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103-366-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2007	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	08/22/2007		

**Labeler** - Pharbest Pharmaceuticals, Inc. (557054835)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-366) , manufacture(16103-366) , pack(16103-366) , label(16103-366)